510(k) SUMMARY.

510(k) nmbr: (unassigned)

Submitted by: TriMed, Inc.
25768 Parada Drive
Valencia, California 91355
800-633-7221

Prepared by: Robert J. Medoff, MD
Contact person: Robert J. Medoff, MD
Date prepared: December 29, 2003
Proprietary Name: TriMed Bearing Plate
TriMed Volar Bearing Plate

Classification Name: Bone fixation plates
Common/Usual Name: TriMed Bearing Plate
TriMed Volar Bearing Plate
(other names reserved for future sites of application)

Sample Predicate Devices:

Zimmer Forte plate

Synthes bone fixation plates

Smith-Nephews bone fixation plates and screws

Spinal Concepts Acufix Cervical Plate System, (regulation number 888.3060, issued by FDA 9/9/99)

Hand Innovations Distal Volar Radial Plate

TriMed plates

Class: II, Sec. 888.3030 Bone fixation plate

Classification Panel: These devices are reviewed by an orthopaedic panel (888)

Product Code: HRS

Description of the device:

The TriMed Bearing Plate is a bone fixation plate that is used as an aid to fracture fixation. The plates are manufactured from either medical grade 316 stainless steel (ASTM F138, ASTM F139) or medical grade wrought Titanium-6Aluminum-4Vanadium alloy (ASTM F136). Detailed dimensional characteristics of the devices are provided in enclosures 8 and 9.

Intended use of the Device:

The TriMed Bearing Plate is intended for use as an aid to fracture healing. The implants are applied to a fracture bone and secured with bone screws and threaded or unthreaded locking fixation pegs.

Technological characteristics:

The TriMed Bearing Plate has identical technical characteristics to existing bone plates in common use. Sample existing implant sales literature is supplied with enclosure 5 of the 510(k) application, and material specification sheets are supplied with enclosure 6 of the 510(k) application.

Indications for use:

The TriMed Bearing Plate is indicated for:

1. Fixation of fractures or non-unions of the distal radius
2. Osteotomies of the distal radius to correct malunion

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2004

Robert J. Medoff, MD
TriMed, Inc.
25768 Parada Drive
Valencia, California 91355

Re: K040112
Trade/Device Name: TriMed Bearing Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: December 29, 2003
Received: January 20, 2004

Dear Dr. Medoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Supplement A to the 510(k) application for the TriMed Bearing Plate

Indication for Use Form

510(k) Number (if known): K040112

Device Name: TriMed Bearing Plate

Indications for Use:

1. Fixation of fractures or non-unions of the distal radius

2. Osteotomies of the distal radius to correct malunion

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ OR Over-The-CounterUse
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040112